# **BMJ Open** Cohort profile: The Bariatric Experience Long Term (BELONG): a long-term prospective study to understand the psychosocial, environmental, health and behavioural predictors of weight loss and regain in patients who have bariatric surgery

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# ABSTRACT

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Correspondence to Dr Karen J Coleman; Karen.J.Coleman@kp.org **Purpose** The Bariatric Experience Long Term (BELONG) prospective study cohort was created to address limitations in the literature regarding the relationship between surgical weight loss and psychosocial, health, behaviour and environmental factors. The BELONG cohort is unique because it contains 70% gastric sleeve and 64% patients with non-white race/ethnicity and was developed with strong stakeholder engagement including patients and providers.

**Participants** The BELONG cohort study included 1975 patients preparing to have bariatric surgery who completed a baseline survey in a large integrated health system in Southern California. Patients were primarily women (84%), either black or Hispanic (59%), with a body mass index (BMI) of 45.1±7.4 kg/m<sup>2</sup>, age 43.3±11.5 years old, and 32% had at least one comorbidity.

**Findings to date** A total of 5552 patients were approached before surgery between February 2016 and May 2017, and 1975 (42%) completed a baseline survey. A total of 1203 (73%) patients completed the year 1 and 1033 (74%) patients completed the year 3 postoperative survey. Of these survey respondents, 1341 at baseline, 999 at year 1, and 951 at year 3 were included in the analyses of all survey and weight outcome data. A total of 803 (60% of eligible patients) had survey data for all time points. Data collected were self-reported constructs to support the proposed theoretical model. Height, weight and BMI were abstracted from the electronic medical record to obtain the main outcomes of the study: weight loss and regain.

**Future plans** We will collect self-reported constructs and obtain height, weight and BMI from the electronic medical record 5 years after bariatric surgery between April 2022 and January 2023. We will also collect patient experiences using focus groups of 8–12 patients each throughout 2022.

# STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ One of the main strengths of the Bariatric Experience Long Term (BELONG) cohort study is it is one of the largest longitudinal mixed-methods (medical record, survey and qualitative data) studies of bariatric patients that was designed using a comprehensive theoretical model of factors related to surgical weight loss.
- ⇒ Another main strength is the BELONG cohort study contains a large sample of gastric sleeve patients (70%), the most common bariatric operation in the USA and has mostly patients with diverse racial and ethnic backgrounds (59%).
- ⇒ Finally, the involvement of bariatric patients in the design and implementation of the study is a strength and unique aspect of the study.
- ⇒ Some of the main limitations of the BELONG cohort are the low enrolment rate in the cohort (42.4%) and only 60% of survey respondents had survey data at every time point.
- ⇒ Finally, the year 3 survey was conducted, and year 5 survey will be conducted, during the beginning of the COVID-19 outbreak and thus any conclusions about the impact of bariatric surgery on survey variables and weight loss/regain need to be understood within the context of the global pandemic.

# **INTRODUCTION**

Severe obesity (body mass index (BMI)  $>35 \text{ kg/m}^2$ ) has increased in prevalence over the past several decades.<sup>1</sup> Unfortunately, intensive, multicomponent lifestyle interventions have had a minimal impact on severe obesity.<sup>2</sup> These outcomes have led to

the development of surgical treatments, referred to as bariatric surgery, for severe obesity. Studies have found that when compared with conventional weight loss strategies, bariatric surgery resulted in much higher weight loss over a period of 2–5 years.<sup>3–6</sup> For patients with severe obesity, bariatric surgery may become the treatment of choice.

There is large variation in weight loss outcomes even within the same bariatric operation. The largest longitudinal cohort study on bariatric patients, the Longitudinal Assessment of Bariatric Surgery (LABS), has identified five weight change trajectories following a single standardised operation, that ranged from 56% total weight loss (%TWL) to 1% gain.<sup>7</sup> By 1 year, almost 25% of all patients in the LABS Study began to regain the weight they had lost. We have also shown wide variability in surgical weight loss from less than 10% to over 40% TWL.<sup>8</sup> Some of this variability may be due to between-patient differences. For example, some black and Hispanic patients do not lose as much weight as their white counterparts.<sup>9–12</sup> Given the wide range in weight loss outcomes following the same operation, it is imperative to understand the factors predicting this variability to improve outcomes for all patients.

In attempting to understand correlates or predictors of bariatric surgical outcomes, there are two general foci in the literature to date: immutable patient characteristics such as demographics and bariatric operation type<sup>9 13–16</sup>; and modifiable factors such as health behaviours, weight before surgery, mental health and social support.<sup>17–31</sup> In general, the immutable characteristics have been studied in the preoperative period (if studies have baseline data) and modifiable factors have been studied both before and after surgery. Most of the work on modifiable factors is not grounded in psychosocial theoretical models or theories of health behaviour change.<sup>32</sup> Few attempts have been made to present a unified, comprehensive model of multiple factors that could predict bariatric weight loss and regain.

The Bariatric Experience Long Term (BELONG) prospective mixed-methods cohort study was designed to address these limitations by applying a comprehensive theoretical model of health behaviour change (please see figure 1) to the collection of self-reported survey

# PRE-SURGICAL (Baseline)

# POST-SURGICAL (12-, 36-, 60-Months)

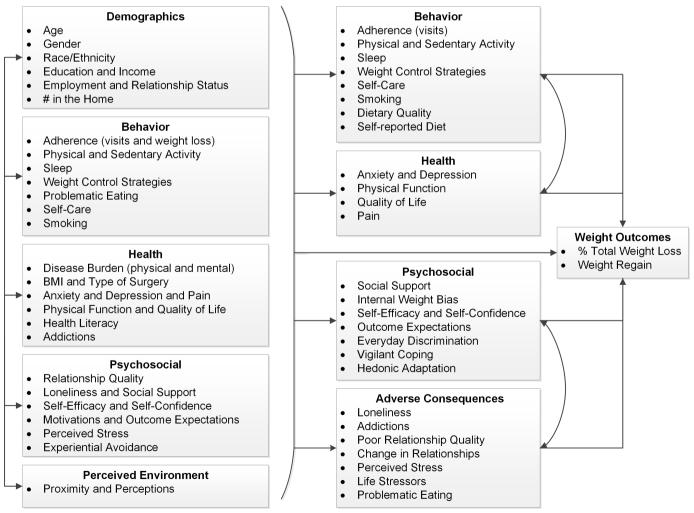


Figure 1 Theoretical model upon which the Bariatric Experience Long Term Study is based. BMI, body mass index.

data and qualitative patient experiences before surgery and up to 5 years after surgery to understand weight loss and regain. Our approach to the study of predictors of bariatric weight loss was based on the suggestions of Elder and colleagues<sup>33</sup> and Noar and Zimmerman<sup>34</sup> that a unified approach be used across the common elements of theories of behaviour change, and that these elements be directly relevant to the healthcare setting.<sup>33</sup> We also applied findings from published research on factors related to successful behaviour change<sup>35-37</sup> and weight loss using other treatment modalities such as diet and exercise.<sup>38 39</sup> Finally, a special emphasis was placed on understanding the experiences of black and Hispanic patients and why they may lose less weight than their white counterparts. Constructs such as everyday racism<sup>40</sup> and vigilant coping<sup>41</sup> were added to both survey and qualitative data collection to address this question.

Based on our a priori theoretical model, we hypothesised the following: (1) baseline predictors of weight loss/regain would be BMI, race/ethnicity, gender, social support, perceptions of the nutrition and physical activity (PA) environment, binge eating and disease burden/ severity; (2) the effects of baseline predictors on weight loss/regain will be mediated by changes in social support, health behaviours and problematic eating; (3) the effects of both baseline and follow-up predictors in weight loss/ regain will be mediated by the development of adverse psychosocial consequences.

For black and Hispanic patients, we also hypothesised that: (1) black and Hispanic patients will lose less and regain more weight compared with white patients *mediated by*: low socioeconomic status; living in neighbourhoods with high crime and poverty rates; higher comorbidity burden; lower utilisation of follow-up care; higher rates of internalised racism, depression, anxiety and stress; and use of vigilance and food to cope with stress; and (2) Hispanic patients will lose more and regain less weight than black patients, which will be *mediated by*: living in majority Hispanic neighbourhoods, higher socioeconomic status, greater use of postoperative care services, lower internalised racism and less frequent use of vigilant coping to deal with stress.

The purpose of the qualitative component of the BELONG Study was to explore in greater depth than allowed in questionnaires the sociocultural norms, health behaviours and environmental factors associated with a patient's weight loss/regain. The qualitative and quantitative components of the BELONG Study will be combined using the QUAN+QUAL structure in Palinkas and colleagues' mixed-methods framework,<sup>42</sup> here both sources of data have equal importance in the exploration of a phenomenon. Once analyses are complete, we will be able to address if our a priori theoretical model of bariatric weight loss/regain in diverse patients is appropriate or should be revised. Results from our work will provide the evidence needed to design patient-centred, culturally appropriate preoperative preparation and postoperative care programmes so that all patients achieve

the maximum benefits from this highly effective treatment for severe obesity.

# **COHORT DESCRIPTION**

# Study design

The BELONG Study was designed as a prospective mixed-methods longitudinal cohort study. The qualitative component of the study was designed to address the bariatric experience of weight loss for racial and ethnic groups of patients, men, and those who lost or did not lose and maintain at least 20% TWL. A 20% TWL threshold was chosen based on our own work that this amount of weight loss is important for the remission of diabetes.<sup>43</sup> All study methods were designed with a patient and provider as part of the study team and a stakeholder advisory group of diverse post-bariatric patients. The stakeholder advisory board was specifically focused on addressing issues of structural racism, discrimination and stigma specific to bariatric surgery.

# **Participants**

# Enrolment and baseline survey completion

Eligibility criteria for inclusion in the BELONG mixedmethods cohort study were: (1) being enrolled in a 12-week bariatric surgery preparation course; (2) planning to have a first bariatric operation within 6 months of the baseline survey; (3) being an adult 18 years of age and older; and (4) meeting general eligibility criteria for weight loss surgery in the USA.<sup>44</sup> Figure 2 provides the recruitment flow for the study. Recruitment for the survey began in February 2016 and ended in May 2017. Table 1 provides baseline differences in descriptive variables available from the electronic medical record between those who were enrolled in the cohort (n=1975; 42% response rate), and the patients who were eligible and contacted but not enrolled (n=1239) and those who were contacted but not enrolled because they were determined to be ineligible after they were contacted (n=2338). Self-reported survey data were not available for those who were not enrolled.

In addition to the assessment of eligibility at the time of outreach and survey administration, eligibility was also assessed after the collection of the baseline and year 1 surveys, which further reduced the number of survey respondents who could be used for outcome analyses. Reasons for this second eligibility assessment are shown in figure 2. Of the 1975 patients who were surveyed at baseline, 634 patients were determined as ineligible for all years of the study primarily because: they never had surgery (n=294), they had surgery before the baseline survey (n=68) or they had surgery more than 6 months after the baseline survey (n=272). Many of these exclusions were made after patients had completed surveys because of the delays in receiving surgery, reporting errors in the electronic medical record and delays in case validation. After applying all exclusions (please see figure 2), there were 1341 patients who were considered

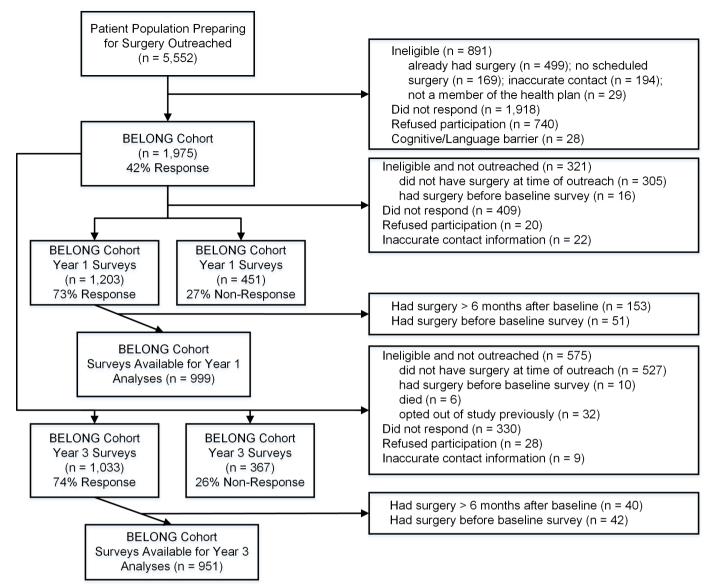


Figure 2 The Bariatric Experience Long Term (BELONG) Study cohort recruitment, enrolment, and follow-up for year 1 and year 3 surveys. Differences between different groups of patients in this study flow are shown in tables 1 and 2.

eligible for the study and used as the baseline analytical cohort for follow-up. Baseline data for these patients are shown in table 2.

# Follow-up survey completion

Patients were surveyed at 1 year (between April 2017 and January 2019) and 3 years (between May 2019 and January 2021) after they had bariatric surgery (note the surgery date could have been up to 6 months after the baseline survey). A survey at 5 years is also planned (between April 2022 and January 2023). In addition, weight (lbs), height (inches) and BMI (kg/m<sup>2</sup>) were abstracted from the electronic medical record at all time points. Survey response rates for each year of follow-up were 73% (n=1203) for year 1 and 74% (n=1033) for year 3 (see figure 2). Qualitative interviews began in April 2021 and were completed in March 2022 (n=68). In addition, focus groups with 8–10 patients each will be conducted throughout 2022.

# Eligible cohort for weight outcome analyses

Not all patients were eligible for outcome analyses. There were 803 patients (60% of those eligible) who had survey data for all time points (baseline, year 1 and year 3). Table 2 provides descriptive statistics for the patients eligible for the outcome analyses. Data are presented for those patients with a baseline survey (n=1341) compared with those who had a year 1 survey (n=999) and a year 3 survey (n=951).

# Measures

# Survey

All surveys for the BELONG Study were administered using a Computer-Aided Telephone Interview system or a self-directed website and took approximately 75 min to complete. The baseline survey was for research only and was not used in the patient's preparation/decision process for surgery. Half (n=978; 50%) of all survey respondents

	Envelled	Refused or non-		ha a lia 'la la	Total
	Enrolled	response		Ineligible	outreached
	1975	2686	P value	891	5552
Women	1660 (84%)	2071 (77%)	< 0.001	712 (80%)	4443 (80%)
Race/ethnicity		47 (00()	<0.001	44 (00()	07 (00()
Asian	26 (1%)	47 (2%)		14 (2%)	87 (2%)
Black	344 (17%)	580 (29%)		158 (18%)	1082 (19%)
Hispanic	838 (42%)	1222 (45%)		389 (44%)	2449 (44%)
Native American Alaskan	8 (<1%)	8 (<1%)		2 (<1%)	18 (<1%)
Pacific Islander	10 (<1%)	20 (<1%)		6 (<1%)	36 (<1%)
White	716 (36%)	764 (28%)		307 (34%)	1787 (32%)
Multiple	11 (<1%)	9 (<1%)		3 (<1%)	23 (<1%)
Other	10 (<1%)	16 (<1%)		8 (<1%)	34 (<1%)
Unknown	12 (<1%)	20 (<1%)		4 (<1%)	36 (<1%)
Age (years)	43.3±11.6	44.8±8.0	0.43	43.3±8.2	44.7±7.9
Age categories (years)			0.09		
18–29	250 (13%)	337 (13%)		102 (11%)	689 (12%)
30–39	565 (29%)	751 (28%)		248 (28%)	1564 (28%)
40–49	550 (28%)	822 (31%)		248 (28%)	1620 (29%)
50–64	543 (27%)	663 (25%)		257 (29%)	1463 (26%)
65+	67 (3%)	110 (4%)		36 (4%)	213 (4%)
Body mass index (BMI) (kg/m²)	45.1±7.4	44.8±8.0	0.20	43.3±8.2	44.7±7.9
BMI categories (kg/m <sup>2</sup> )			0.002		
30–34.99	62 (3%)	145 (5%)		74 (8%)	281 (5%)
35–39.99	447 (23%)	616 (23%)		204 (23%)	1267 (23%)
40–49.99	1026 (52%)	1314 (49%)		422 (47%)	2762 (50%)
50–59.99	351 (18%)	451 (17%)		120 (13%)	922 (17%)
60+	85 (4%)	132 (5%)		35 (4%)	252 (5%)
Comorbidity burden			0.55		(1,1)
0	932 (47%)	1243 (46%)	0.00	417 (47%)	2592 (47%)
1–2	939 (48%)	1309 (49%)		411 (46%)	2659 (48%)
3+	104 (5%)	134 (5%)		63 (7%)	301 (5%)
Type 2 diabetes	478 (24%)	587 (22%)	0.06	178 (20%)	1243 (22%)
Hypertension	311 (16%)	534 (20%)	<0.001	158 (18%)	1003 (18%)
	Enrolled	Refused or non- response		Ineligible	Total
	1975	2686	P value	891	5552
Mantal illingen		2000		001	0002
Mental illness	132 (70/)	127 (50/)	0.001	59 (70/)	207 (60/)
Serious mental illness	132 (7%)	137 (5%)		58 (7%)	327 (6%)
Severe anxiety/depression	178 (9%)	188 (7%)		75 (8%)	441 (8%)
Mild-to-moderate anxiety/depression	741 (38%)	965 (36%)		344 (39%)	2050 (37%)
Substance abuse/eating disorder	13 (<1%)	20 (<1%)		5 (<1%)	38 (<1%)
None	911 (46%)	1376 (51%)		409 (46%)	2696 (49%)
Weight loss (lbs) in year before surgery/survey		15.6±16.2	< 0.001	16.2±16.3	14.7±15.4
Scheduled visit attendance (%) in year before surgery/survey (range 0%–100%)	76±13	73±14	<0.001	72±13	74±14

Data are shown for those who were outreached for the study based on initial eligibility (n=5552). Why patients were not eligible is in figure 2.

Table 2Descriptive statistics for the Bariatric Experience Long Term mixed-methods study cohort in each survey period:<br/>baseline survey cohort (n=1975), baseline analytical sample (n=1341), year 1 analytical sample (n=999) and year 3 analytical<br/>sample (n=951)

	Baseline (n=1341)	Year 1 (n=999)	P value*	Year 3 (n=951)	P value*
Women	1150 (86%)	860 (86%)	0.92	824 (87%)	0.73
Race/ethnicity					
Hispanic	504 (38%)	370 (37%)	0.75	345 (36%)	0.41
White	440 (33%)	340 (34%)	0.45	324 (34%)	0.43
Black	196 (15%)	137 (14%)	0.38	134 (14%)	0.61
Native American/Alaskan Native	17 (1%)	12 (1%)	0.81	9 (1%)	0.27
Asian	9 (<1%)	6 (<1%)	0.58	7 (<1%)	0.75
Native Hawaiian/Pacific Islander	18 (1%)	15 (1.5%)	0.65	14 (1.5%)	0.65
Mixed	127 (10%)	96 (10%)	0.86	98 (10%)	0.35
Other	29 (2%)	22 (2%)	0.86	19 (2%)	0.70
Unknown	1 (<1%)	1 (<1%)	0.79	1 (<1%)	0.74
Age (years)	43.4±11.3	43.8±11.6	0.02	43.8±11.6	0.04
Age categories (years)					
18–29	160 (12%)	117 (12%)	0.81	114 (12%)	0.92
30–39	385 (29%)	278 (28%)	0.53	265 (28%)	0.57
40–49	384 (29%)	274 (27%)	0.42	259 (27%)	0.32
50–64	371 (28%)	295 (30%)	0.21	282 (30%)	0.18
65+	41 (3%)	35 (3.5%)	0.38	31 (3%)	0.65
Socioeconomic status (range 8–67)	38±13	38±12	0.40	39±13	<0.001
Body weight (lbs)	262.5±48.1	261.0±47.9	0.06	261.9±47.2	0.53
Body mass index (kg/m <sup>2</sup> )	43.1±6.4	42.9±6.4	0.07	43.1±6.5	0.81
Body mass index categories (kg/m <sup>2</sup> )					
30–34.99	76 (6%)	59 (6%)	0.74	59 (6%)	0.44
35–39.99	401 (30%)	302 (30%)	0.84	275 (29%)	0.51
40–49.99	685 (51%)	510 (51%)	1.00	488 (51%)	0.92
50–59.99	157 (12%)	113 (11%)	<0.001	112 (12%)	0.92
60+	22 (2%)	15 (1.5%)	0.65	17 (2%)	0.68
Comorbidity burden (# of conditions)					
0	494 (37%)	359 (36%)	0.58	356 (37%)	0.72
1–2	671 (50%)	506 (51%)	0.76	466 (49%)	<0.001
3+	176 (13%)	134 (13%)	0.76	129 (13.5%)	0.65
Type 2 diabetes	375 (28%)	285 (28.5%)	0.68	263 (28%)	0.84
Hypertension	430 (32%)	326 (33%)	0.70	312 (33%)	0.63
Mental illness burden					
Serious mental illness	150 (11%)	119 (12%)	0.43	108 (11%)	0.86
Severe anxiety/depression	46 (3%)	34 (3%)	1.00	33 (3.5%)	0.89
Mild-to-moderate anxiety/depression	450 (34%)	329 (33%)	0.71	325 (34%)	0.71
Substance abuse/eating disorder	1 (<1%)	0	1.00	1 (<1%)	0.74
None	694 (52%)	517 (52%)	1.00	484 (51%)	0.65
	Baseline (n=1341)	Year 1 (n=999)	P value*	Year 3 (n=951)	P value*
Type of surgery					
Sleeve gastrectomy	938 (70%)	693 (39%)	0.79	652 (69%)	0.53
Roux-en-Y gastric bypass	400 (30%)	305 (30.5%)	<0.001	297 (31%)	0.35
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	Baseline (n=1341)	Year 1 (n=999)	P value*	Year 3 (n=951)	P value*
Other	3 (<1%)	1 (<1%)	0.14	1 (<1%)	0.18
% Total weight loss year before surgery	6.6±4.6	6.6±4.6	0.35	6.7±4.7	0.04
Scheduled visit attendance (%) year before surgery (range 0%–100%)	77±11	77.5±11	0.04	78±11	0.006
% Total weight loss at 1 year (outcome)	25.8±9.0	26.3±8.7	<0.001	26.2±8.9	0.006
Body mass index at 1 year (kg/m <sup>2</sup> )	32.1±5.9	31.8±5.8	0.001	32.0±5.9	0.16
Weight at 1 year (lbs)	194.3±41.8	191.9±40.4	<0.001	192.9±40.6	0.05
% Total weight loss at 3 years (outcome)	22.2±10.5	22.7±10.4	0.005	22.6±10.5	0.06
Body mass index at 3 years (kg/m <sup>2</sup> )	33.5±6.4	33.2±6.2	0.001	33.4±6.3	0.20
Weight at 3 years (lbs)	203.5±43.9	200.9±42.3	<0.001	202.0±42.2	0.06

The formation of each of these analytical samples is shown in figure 2. \*Compared with baseline analytical cohort.

completed the baseline survey using the website and by year 3 this had increased to 70% (n=719).

Surveys asked patients to self-report the following information which is presented by model construct in figure 1. Demographic: gender, race/ethnicity, education, income, employment and relationship status, number of people in the home and socioeconomic status (SES) as calculated with the Hollingshead Index of Social Status (uses education and occupation code).<sup>45</sup> Behaviour. adherence measured as attendance at scheduled outpatient visits (12 months before and throughout follow-up) and %TWL in the 12 months before surgery,<sup>18</sup> physical<sup>46</sup> and sedentary<sup>47</sup> activity, sleep,<sup>48</sup> weight control strategies,<sup>49</sup> problematic eating (binge eating<sup>50</sup>; loss of control, restrained and emotional eating<sup>51</sup>; self-care<sup>52</sup>; smoking<sup>46</sup>; dietary quality<sup>53</sup> and brief dietary intake<sup>54</sup>). *Health*: symptoms of anxiety<sup>55</sup> and depression,<sup>56</sup> pain,<sup>57</sup> physical function,<sup>58</sup> quality of life,<sup>59</sup> health literacy,<sup>60</sup> and addictions such as lifetime drug use,<sup>61</sup> alcohol use disorder,<sup>62</sup> gambling,<sup>63</sup> prescription/illicit drug abuse<sup>63</sup> and food.<sup>64</sup> Psychosocial: relationship quality,<sup>65</sup> motivations for having surgery and weight loss expectations after surgery,66 weight loss selfefficacy,<sup>67</sup> loneliness,<sup>68</sup> perceived stress,<sup>69</sup> experiential avoidance,<sup>70</sup> positive and negative social support for physical activity and healthy eating,<sup>71</sup> self-confidence for exercise,<sup>72</sup> internal weight bias (only in year 3 and 5 surveys),<sup>73</sup> vigilant coping style (only in year 3 and 5 surveys),<sup>41</sup> everyday discrimination (only in year 3 and 5 surveys)<sup>40</sup> and hedonic adaptation (only in year 1, 3 and 5 surveys).74 Perceived environment: perceptions of neighbourhood environment for promotion of healthy behaviours and neighbourhood proximity of healthy alternatives.<sup>75</sup>

In addition to the broad constructs in figure 1, investigators from the BELONG Study were also interested in the development of an *adverse consequences* construct after bariatric surgery. This construct used elements of the *health, psychosocial and behaviour* constructs which included the development of loneliness, addictions, problematic eating, and poor relationship quality and loss of relationships (eg, divorce/separation) as well as increases in stress.

# Electronic medical record

The following information was abstracted from the electronic medical record at the time of surgery or the baseline survey: diagnoses and pharmacy records to determine disease burden both physical and mental health related, adherence to scheduled visits for routine medical care in the year before surgery/survey, weight and height to determine both BMI and %TWL in the year before surgery/survey, and date of birth to calculate age. For the follow-up time periods, we abstracted weight and height to determine BMI and %TWL. Height and weight were collected by clinical staff as part of routine clinical care.

# Qualitative interviews and focus groups

Oualitative interview protocols were designed with the patient stakeholder advisory board and designed to address critical time periods of bariatric surgery: the year before the operation, the 12-24 months after surgery and the longer term period of 3-5 years after surgery. Patients were interviewed at 3-5 years after surgery and thus were asked to recall before surgery and 12-24 month time points. Across each of these time points, interview domains included personal/family social network, healthcare teams/health system and society. Special emphasis was placed on understanding racism and stigma in each domain, and we asked about how the pandemic was affecting their weight loss. These domains were chosen based on the study theoretical model presented in the introduction (see figure 1), with modifications from our stakeholders. Interviews were 60-90 min each and patients could have up to two interviews each (total time=120 min).

# Patient and public involvement

From the inception of the study, a bariatric provider and a bariatric patient were included as members of the scientific team. They attend all study meetings and are included as authors in all publications. To create the qualitative study methods, a patient advisory board was formed to design, test and interpret the data. These advisors were recruited through a network of providers and health system leaders and were either: (1) already engaged in designing the health system programme for preoperative and postoperative care and monitoring, or (2) leading preoperative and postoperative patient support groups. Patients were diverse in race/ethnicity (black, white and Hispanic) and were an equal mix of men and women. Patients also ranged in time out from bariatric surgery from 1 to 10 years. In addition to design, implementation and interpretation of both qualitative and survey data, the patient advisory board, and the patient and provider co-investigators, will be involved in planning and executing the dissemination of the findings for clinical and professional audiences.

# FINDINGS TO DATE

# Participants

Descriptive information for the enrolled cohort (n=1975) is shown in table 1. In general, when compared with patients who refused participation or did not respond to outreach, patients who completed a baseline survey were more likely to be women (84% vs 77%; p<0.001), white (36% vs 28%; p<0.001), have a BMI of  $40-49.99 \text{ kg/m}^2$ (52% vs 49%; p=0.002), have a mental illness (54% vs 49% p=0.001) and less likely to have hypertension (16%) vs 20%; p<0.001). Those who completed the baseline survey lost less weight (12.9 vs 15.6 lbs; p<0.001) and had higher attendance at scheduled outpatient visits in the year before surgery (76% vs 73%; p<0.001) when compared with patients who did not respond or refused participation. Characteristics for baseline and follow-up survey participants used in the outcome analyses are shown in table 2 (baseline (n=1341), year 1 (n=999) and year 3 (n=951)). Although there were statistically significant differences between patients in the baseline survey sample compared with the follow-up samples, because of the large sample size, these differences were not clinically meaningful (eg, an age difference of 0.4 years or a %TWL difference of 1%).

# Electronic medical record data

Data from the electronic medical record are shown in table 2. At the time of surgery, patients had a BMI of  $43.1\pm6.4$  kg/m<sup>2</sup> primarily in the 40-49 kg/m<sup>2</sup> (51%) range, most had at least one comorbidity (63%) with 28% and 32% having type 2 diabetes mellitus and hypertension, respectively. Fourteen per cent had a serious mental illness and 34% had mild-to-moderate anxiety and depression. Patients lost  $6.6\%\pm4.6\%$  of their weight in the year before surgery and  $25.8\%\pm9.0\%$  at year 1 and  $22.2\%\pm10.5\%$  at year 3 after surgery.

#### Survey data

Baseline demographics for the analytical cohort (n=1341) are shown in table 2 and survey variables are shown in

table 3. In general, the baseline analytical cohort was primarily women (86%), Hispanic or black (53%), 43±11 years old equally distributed across three age categories (30-39, 40-49, 50-54 years old), had at least some college education (81%) with an annual income of at least \$51000 (55%), a mid-range SES (38±13; range 8–67), and the majority were employed outside the home (82%) and were in a relationship (72%). In general, patients in the baseline analytical cohort had high health literacy (88%), never smoked (70%), had low self-reported dysfunction (9±8 out of a total score of 48 with higher numbers reflecting more dysfunction), low levels of depression (5±5 out of 24), anxiety (4±4 out of 21) and pain (7±3 out of 15) symptoms. Patients rated their overall health at 67±21 out of a possible score of 100. Some patients reported having a history of addiction (10%-18%), with few reporting current symptoms of problems with alcohol (9%), gambling (5%) or drugs (1%). If patients were in a relationship, they were generally satisfied with that relationship (17.5±3.5 out of 22). The mean selfreported goal weight loss (expressed as %TWL) was 42%±19% and the mean self-reported weight loss that patients indicated would be disappointing was 25%±27% TWL. As mentioned previously, the actual postoperative %TWL for these patients was 25.8%±9.0% at year 1 and 22.2%±10.5% at year 3.

Patients reported low levels of loneliness  $(32\pm11 \text{ out of } 80)$  and moderate perceived stress  $(22\pm6 \text{ out of } 50)$ . Self-confidence for exercise was moderate to high  $(3\pm1 \text{ out of } 5)$ , self-efficacy for weight loss was high  $(32\pm6 \text{ out of } 40)$  and positive social support for healthy behaviours was also high  $(20\pm8 \text{ out of } 30)$  going into surgery. The most common motivations patients reported for having surgery were to improve their health (96%), to do the things they wanted to do (93%), feel better about themselves (88%), do things that friends and family could do (79%), and to play with their children/grandchildren (76%).

Over 20% of patients reported symptoms of binge eating with fewer reporting night eating (10%) or night snacking (13%) before surgery. Patients reported loss of control of (21±8 out of 43), restrained (19±4 out of 27) and emotional eating behaviours ( $8\pm4$  out of 15). In general, patients reported good sleep quality (77% better/somewhat better) and efficiency (85%±17% out of 100%). Almost half (48%) reported meeting guidelines for moderate-to-vigorous physical activity (173±157 minutes/week) and an average of 1±2 and 2±2 days per week of strength and flexibility training, respectively. The most common weight control strategies patients reported using before surgery were setting healthy eating goals (76%), eating smaller portions (76%), eating breakfast regularly (71%), eating three meals a day/eating regularly (70%) and using a monitoring device (64%). Only 17% of patients indicated that they used all weight control strategies at least most of the time/always. Finally, most patients felt that locations in their neighbourhoods like grocery stores and parks were accessible (4±2 out of 7 with higher scores Table 3Descriptive statistics from the survey for thepatients in the baseline analytical cohort (n=1341)

Survey variable	n (%) or mean±SD
Demographic construct (in addition to variables in table 2)	
Education (% with some college or higher)	1080 (81)
Annual income (≥ \$51 000)	734 (55)
Socioeconomic status (range 8-67)	38±13
Employed	1102 (82)
In a relationship	961 (72)
Live alone	107 (8)
# Living in the home	
Behaviour construct (in addition to variables in table 2)	
Physical activity	
Moderate-to-vigorous physical activity (MVPA), min/week	173±157
Meet guidelines for MVPA (150 min/week)	650 (48)
Strength training, days/week	1±2
Flexibility exercise, days/week	2±2
Sedentary activity, min/day	226±206
Sleep	
Poor sleep quality (% better/somewhat better)	1033 (77)
Sleep efficiency (range 0%-100%)	85±17
Weight control strategies (% used most of the time/always)	
Sets healthy eating goals	1014 (76)
Sets exercise goals	749 (56)
Sets weight goals	673 (50)
Reward for meeting goals	304 (23)
Adjusts goals if not met	448 (33)
Plans for problems that interfere with goals	705 (53)
Makes daily/weekly exercise/meal plans	746 (56)
Weighs daily/weekly	850 (63)
Keeps record of behaviour	724 (54)
Graphs behaviour	432 (32)
Uses reminders to exercise/eat healthy	786 (59)
Avoids places where overeats/does not eat healthy	601 (45)
Exercises with friends/family	351 (26)
Does not keep unhealthy food/drinks at home	733 (55)
Uses smaller plates for meals	777 (58)
Eats smaller portions	1014 (76)
Does not snack between meals	621 (46)
Eats breakfast regularly	954 (71)
Tries to eat three meals/day regularly	937 (70)
Frequency of all weight control strategies used most of the time/always	231 (17)
Used a self-monitoring device in last 30 days	864 (64)
Total weight control strategies used $\geq$ 50% (range 0–19)	13±4
Problematic eating	
Binge eating	276 (21)
Night eating	129 (10)
Night snacking	172 (13)
Loss of control of eating (range 9-43)	21±8
	Continued

# Table 3 Continued

Table 3   Continued	
Survey variable	n (%) or mean±SD
Restrained eating (range 6–27)	19±4
Emotional eating (range 3–15)	8±4
Self-care (range 4–20)	13±5
Smoking	
Never smoked	934 (70)
Quit	385 (29)
Current smoker	15 (1)
Health construct (in addition to variables in table 2)	
Anxiety symptoms (range 0–21)	4±4
Depression symptoms (range 0–24)	5±5
Pain (range 3–15)	7±3
Total dysfunction in last 30 days (range 0-48)	9±8
Quality of life rating (range 0–100)	67±21
High health literacy (% total score of 3)	1185 (88)
Addictions	
Any lifetime addictions	239 (18)
Any lifetime problems with prescription medication	137 (10)
Alcohol use/abuse (% moderate to severe risk)	122 (9)
Gambling problem (% possibly)	62 (5)
Problem with drug use (% possibly)	13 (1)
Food addiction (% experienced these symptoms)	
Consuming greater amounts for longer periods of time	310 (23)
Tried quitting certain foods	147 (11)
More time to obtain	377 (28)
Give up things to obtain food	265 (20)
Experience withdrawal	277 (21)
Significant impairment/distress	146 (11)
Psychosocial construct	
Relationship quality (range 1-22)	17.5±3.5
Loneliness (range 20–80)	32±11
Positive social support (range 6–30)	20±8
Weight loss self-efficacy (range 8-40)	32±6
Self-confidence for exercise (range 1–5)	3±1
Motivations for surgery (% important/very important)	
Improve appearance	688 (51)
New clothes	749 (56)
Outcome expectations for weight loss	
Goal % total weight loss (%TWL) after surgery	42±19
Disappointing %TWL after surgery	25±27
Perceived stress (range 10-50)	22±6
Experiential avoidance (range 15-75)	43±11
Perceived environment construct	
Perception of neighbourhood proximity (range 0-7)	4±2
Perception of neighbourhood as healthy (range 11-55)	38±7
Data for variables from the electronic medical record for this col- provided in table 2. The theoretical model illustrating the domain in figure 1.	

being more accessible) and moderately healthy  $(38\pm7)$  out of 55).

#### **Previously published work**

Several hundred patients did not have surgery within 6 months of their baseline survey (see figure 1) and thus were not eligible for the analysis of survey and outcome data. In our previously published work, we examined the factors that led BELONG patients to receive or not receive surgery.<sup>76</sup> The strongest predictors of having surgery were being a woman and losing at least 5% TWL in the year before surgery. The strongest predictors of not having surgery were a BMI>50 kg/m<sup>2</sup> and having a higher physical comorbidity burden. Having a mental health condition did not predict if a patient had surgery. These findings highlighted why the uptake of bariatric surgery is extremely low; only 1%-2% of eligible patients have surgery in the USA.<sup>77</sup> Practices such as requiring 5%–10% TWL before surgery and selection of patients with safer operative risk profiles (younger with lower comorbidity burden) may inadvertently contribute to underutilisation of bariatric surgery among some subpopulations<sup>78 79</sup> who could most benefit from this intervention.

#### **Strengths and limitations**

One of the main strengths of the BELONG mixedmethods cohort study is that it is one of the largest longitudinal mixed-methods studies of bariatric patients that was designed using a comprehensive theoretical model of weight loss and includes medical record, survey and qualitative data (see figure 1). The only other comparable study is the LABS Study which enrolled over 2500 patients across the USA and followed patients for more than 7 years.<sup>80</sup> However, in comparison with the LABS Study, the BELONG mixed-methods cohort study contains a large sample of gastric sleeve patients (70%), the most common bariatric operation in the USA<sup>81</sup> and has mostly patients from various racial and ethnic groups (59%). The LABS Study patients were primarily white (90%) and <3% had an operation other than gastric bypass or laparoscopic band. These two distinctions are important because the findings of the BELONG cohort can be applied directly to the current state of bariatric practice and black and Hispanic patients who suffer disproportionately from severe obesity<sup>1</sup> and thus stand the most to gain from bariatric surgery. Despite the promise of this benefit, there are several reports in the literature,<sup>10–12</sup> including our own,<sup>9</sup> that some black and Hispanic patients do not lose as much weight as their white counterparts following surgery. The BELONG mixed-methods cohort study is uniquely positioned to understand the reasons for these disparities.

In addition, the BELONG Study is the first study in this area to have extensive involvement from patients in its design and implementation. Our patient advisory board is instrumental in our selection of variables and outcomes to study and in helping us create patient stories that are meaningful illustrations of the survey findings. Our approach is designed specifically to address gaps in the literature and practice, so that all patients with severe obesity can have the best experience with the most effective treatment available for their condition.

The main limitation of the BELONG cohort is the biased nature of the study sample. These were all patients who were near the end of a preparation course for surgery and thus they were predisposed to have surgery. Our findings may have been different if we had surveyed patients when they were referred for surgery before beginning the course. In addition, we had a low enrolment rate in the cohort (42.4%) further limiting our generalisability. Limiting our generalisability to the bariatric population as a whole was only 60% of survey respondents had survey data at every time point although our response rates were excellent for the 1-year (73%) and 3-year (74%)surveys. Another limitation was that the year 3 survey was conducted during the beginning of the COVID-19 outbreak. Any conclusions about the impact of bariatric surgery on survey responses and weight loss/regain will need to be tempered by the context of a global pandemic. Finally, even though this health system included 23 bariatric surgeons across 9 practices, our findings were based on an insured population in a single health system and may not apply to uninsured patients or other types of bariatric practices and thus should be replicated more systematically in other settings.

#### DATA SHARING AND COLLABORATION

The unpublished data are only available for use through collaboration with the BELONG Study investigators, a data use agreement upon which all parties must agree and external funding. Persons interested in collaborating with the BELONG Study team can contact Dr Karen Coleman (Karen.J.Coleman@kp.org), the lead investigator. We are eager to share this resource with others in collaboration to extend the evidence base for the most effective treatment available for severe obesity.

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Patient consent for publication Not required.

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Provenance and peer review Not commissioned; externally peer reviewed.

**Data availability statement** Data are available upon reasonable request. The unpublished data are only available for use through collaboration with the BELONG sStudy investigators, a data use agreement upon which all parties must agree, and external funding.

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